TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
PUBLIC INTEREST RESEARCH)
GROUP MEETING)

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IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:

STAKEHOLDERS MEETINGS)
PUBLIC INTEREST RESEARCH)
GROUP MEETING)

Room 1A-001
Federal Drug Administration
5100 Paint Branch Parkway
College Park, Maryland

Wednesday,
February 25, 2004

The parties met, pursuant to the notice, at 3:03 p.m.

BEFORE: MS. CINDY SMITH

APPEARANCES:

For United States Department of Agriculture, Animal Plant Health Inspection Service, Biotechnology Regulatory Services:

REBECCA BECH, Associate Deputy Administrator
SUSAN KOEHLER
JOHN TURNER
NEIL HOFFMAN

U.S. Public Interest Research Group:

RICHARD CAPLAN

P R O C E E D I N G S

(3:03 p.m.)

MS. SMITH: Welcome to our stakeholder discussion series on our upcoming environmental impact statement, or EIS, and our revised plant biotech regulation. We thank you for taking time to join us here today. We know your schedule is busy, and we appreciate your time, as well as the thoughts and discussion that you're going to be sharing with us here shortly.

We have essentially two meetings for these briefings. The first is for us to be able to share information about our plans to move forward with the environmental impact statement, as well as amending our plant biotechnology regulations. And the second purpose is to be able to gather diverse and informative input which will support thoughtful and effective decision-making on our part in the development of our new regulations.

We have here from BRS most of our management team, as well as several other members of the staff, and when available, other members of APHIS programs that support BRS may join us from time to time, as well.

I would like to mention two key individuals who have been dedicated to this project, providing full-time management of our work to complete our EIS and our new regulations.

First, John Turner, who you have likely seen in meetings, at least, if you've not worked directly with John. He's a very important member of our leadership team here at BRS, and I'm very pleased to share that he is providing overall leadership to both the development of the EIS and a new plant biotech regulation.

A second individual, which is a new face that you may not have met before, is Michael Wach, who is a recent hire for BRS, as an environmental protection specialist within our Environmental and Ecological Analysis Unit. This is the unit Susan Koehler heads up. That's our recently-established unit.

In addition to possessing a Ph.D. and an environmental law J.D., Michael brings research experience in plant pathology and weed science, as well as legal experience, working on cases involving NEPA, the Clean Water Act, the Clean Air Act, and other environmental statutes.

What I'm going to do at this point is turn this over to John Turner, who is going to provide some more background information. And then we will be able to proceed an open period for you to be able to share any information with us, or to have any kind of discussion you would like.

Thank you.

MR. TURNER: As you probably know, we participated in interagency discussions with our sister agencies, EPA,

FDA, the White House. And while we concluded that the coordinated framework provides appropriate science- and risk-based regulatory approach and has served us well, the Plant Protection Act of 2000 offers a unique opportunity for us to revise our regulations, and potentially to expand our authority, while still leveraging all of the experience that we've gained to date, regulating this technology.

We also concluded some general agreement on how we're going to proceed with our regulatory approach. But still, there is much opportunity for public and stakeholder input as we move forward and develop our regulatory enhancements.

Given this, we would like to have the opportunity to hear your thoughts, as well as some informal give and take of ideas. It's a unique opportunity at this time, because we have not yet started the formal rule-making process. So we're free to speak openly and exchange ideas with stakeholders and the public.

Our discussion will be professionally transcribed for two primary reasons. First, to provide an accurate record of our discussions, to facilitate our ability to capture and refer to your input. And secondly, in the interest of transparency and fairness to all stakeholders, we will be making available, as part of the public record, and potentially on our website, the documentation of all the

stakeholder discussions, so that the public and other stakeholders will have the benefit of each of the discussions that we will be conducting this week.

I should emphasize that while we're happy to share information on the direction we are likely to take during the process, what we will be sharing is our current thinking in BRS. And that during the process, public and stakeholder input will likely influence our thinking.

In addition, other officials at USDA, including our Administrator, the Undersecretary, our Office of General Counsel, and the Secretary can certainly be expected to provide insightful direction.

So while we value all input, it is important for us to recognize that our thinking will likely evolve. So while we may have an enthusiastic discussion today on a particular aspect of the regulation, it's going to be an evolving process.

And finally, on that note, since it's hard to predict exactly what the final regulation will look like, we can at least share some overall priority areas of emphasis that have been used to set direction and will guide us through this process.

One is rigorous regulation, which thoroughly and appropriately evaluates and ensures safety, and is supported by strong compliance and enforcement.

Secondly, transparency of the regulatory process and regulatory decision-making to stakeholders and the public. Critical to public confidence.

Thirdly, scientific-based systems, ensuring the best science is used to support regulatory decision-making to assure safety.

Fourth, communication, coordination, and collaboration with the full range of stakeholders.

And finally, international leadership, ensuring that international biotech standards are science-based, supporting international regulatory capacity-building, and considering international implications of policy and regulatory decisions.

So again, to remind you, we are being professionally transcribed. So you can start with giving your name to the transcribe. And with that, we open up the floor to you, and we can start with the discussions.

MR. CAPLAN: Okay, great. Thanks, John. My name is Richard Caplan, C-A-P-L-A-N. I work here in D.C. with the U.S. Public Interest Research Group, USPIRG, which, for those of you not familiar, is the national routing office for a number of affiliated -- who work on a range of different issues, including consumerized consumer protection issues, everything from safe products, safe toys, banking, and privacy, to democracy and environmental issues.

I have been on staff now, I'm in my fifth year on staff, working, I devote my time between food safety issues and also clean water issues, Clean Water Act enforcement. And I came to PIRG immediately from Public Policy at the University of Michigan, where I produced some research on ag in general, and biotech in particular.

I want to begin by thanking Cindy and the team for holding this series of meetings. I think in general my experience with Cindy, since we met after you came on to BRS, has been in many ways very open to hearing from the number of different stakeholders. And we appreciate that. We appreciate this process, the beginning of this process, and look forward to continuing to work with you. And we are appreciative of having the opportunity to put forward some of our perspectives today, and look forward to hearing from you, as well, about where the department is heading with this process.

I guess before some specific questions or sort of comments that I have on the Federal Register Notice, I guess I wanted to bring up some issues that I have mentioned before in meetings with BRS staff, that I think are relevant. I guess they fall under this sort of category of other issues that come up at the end of the notice.

And that is, I guess primarily, two things. One is our efforts to get information from the agency have been

stifled for quite some time. We have tried to get information from USDA, and we have done it using the Freedom of Information Act, which is, from our perspective, unfortunate that we would have to even go that route. But have tried for some time to get information related to --

(Interruption.)

MR. CAPLAN: On a couple of different fronts we have sought information, and have been unsuccessful for literally years in getting that information. That relates to a couple of different parts of the agency's activities, including, we have asked for information about records of inspections of field trials.

One of the responses that we received from the agency was that in fact there were no records prior to '99, I think, perhaps prior to 2000, which means that for the first 12 or so years the agency is saying that no records at all were kept of the rate of inspections of field trials. Which I think is, with great understatement, a very poor accounting record, if, in fact, true.

And we received no records of inspections conducted after that time, despite the fact that we've asked for this information some time ago.

We've also asked for information related to USDA's response to violations of the field testing regulations. A few years after we submitted that FOIA, the agency did begin

posting some select information on its website, which we appreciate. However, much of the information that was asked for still has never been put on the website or given to us.

We've also, on a number of occasions, asked the agency for changes related to the website that is maintained for USDA by Virginia Tech, information that we think would be very, very useful to the public, to academia, to all interested stakeholders, about how USDA is overseeing its program. But unfortunately, I think a lot of the key suggestions that we've made remain unfulfilled, including information related to even facts as simple as whether or not these field trials are taking place.

So I think there are some very simple things that can be done that would help organizations like PIRG and many of the other interested stakeholders that you will be hearing from, to have a better idea of how this agency operates. And I think some of them are, in fact, quite simple to implement. And I don't know if you have, before I go forward to talk about some specifics of the Federal Register, if there's any comments about why there has been, for example, such a delay in responding to requests for information, or if that's something you need to get back to me on. But I would be happy to hear any comments on that before we go forward.

MS. SMITH: Well, while that's not really what we

came to address, let me just clarify. You had a FOIA request for records of inspections of field trials, and were told that there were no records of inspections?

MR. CAPLAN: I was told that, I believe for the first 12 years there were no records of inspection. And I'm happy, of course, to make, if you don't have that response available --

MS. SMITH: Would you mind providing me a copy of that?

MR. CAPLAN: With pleasure.

MS. SMITH: And then secondly, you said you received no records in terms of the other FOIA request that you put in in terms of compliance?

MR. CAPLAN: Not that there was no response at all. There we received, it was the, I believe the OSTP report that came out at the end of the Clinton Administration that mentioned a certain number of infractions of that type -- 63, whatever that number was. So we asked for those. We were sent, I believe, two.

We were actually sent three things, one of which had nothing to do with our request. It seemed as if it was mistakenly included in the request. And have gone back to the agency many, many times to say we have asked for this information, where is it. And every time we are told it's coming, it's coming.

MS. SMITH: When you say you received three things, was that three shipments of documents?

MR. CAPLAN: No. There was two records, compliance infractions and the response from the agency, and a third piece of paper that was irrelevant.

MS. SMITH: Okay. We'll follow up on that. We've processed boxes of information with respect to that request, so we'll make a note, even though it's not directly related to what we're here for. We'll make a note of that.

And then one thing I would say is that, just in terms of the website, you might be interested in knowing that we're in the process now of advertising to hire a position dedicated in BRS just to manage the website to make the many changes. We have started working with a team internally to prioritize what kinds of changes we want to make, and additional information. And it's important enough that we've decided that we're actually going to hire a position just dedicated to that.

So when we get that person, we will be in a particularly better position to work with you, and make sure that the priorities that you have, in terms of information, that we can factor those into our internal discussions.

MR. CAPLAN: That's great. Thank you. Doug King I think is the name of the person that I've dealt with on many occasions as Virginia Tech, and he has been nothing but

helpful, and very quick to respond to requests for information. But still, there is just a lot missing that he can't get.

Well, on the notice in the Federal Register, there are a couple of just sort of major areas that I would highlight. I don't think that any of my comments or sort of concerns about where this is headed would come as a surprise to anyone here. I'll outline them quickly, and then there are a couple of things for which I have questions and just sort of clarifications about what is here.

I guess I would start on the so-called biofarm issue, the issue of crops engineered to produce pharmaceuticals and industrial chemicals, for which several of the questions posed ask related questions to.

Certainly, as I think, I would assume everyone here knows PIRG's position on the issue, is that these trials should be restricted to non-food crops. And containment is a major issue, and we think that there shouldn't be open-air plantings of crops producing pharmaceuticals and industrial chemicals.

I think that our perspective has given us some unusual allies, I think, for PIRG, including much of the food processing industry. We wish we had them on our side a lot more than we do. But on this particular instance, I think their very legitimate, well-founded concerns about the

risks of this technology to their business echo ours. And not only that, but as you also know, the recent National Academy report on bioconfinement, which also echoed some of the same concerns.

So I think our position I imagine is quite clear to you. I guess what I'm wondering, in part, is, is the agency able, do you feel that the agency is able to -- I'm not an attorney, so I will defer to folks like you, Michael -- is the agency able, in your opinion, to make the statement that these crops should be not allowed to be grown in good crops? Is that something that you think the department has the ability to do?

Certainly you're hearing from some very important stakeholders, like the environmental community, and the consumer community, and the food processing community. You're also hearing from the National Academy that this is the direction that would seem to be prudent to move to. But I'm wondering if you think that the agency legally can, and then also if you think you are going to head in that direction.

MS. SMITH: Without asking lawyers for a specific legal opinion, what I will tell you is that moving to the expanded authorities under Plant Protection Act, particularly looking at the Noxious Weed Authority, that would give us authority directly for food safety and human

health. And that would put us in a position to really enhance what kinds of requirements or restrictions be placed on field testing for pharmaceuticals and industrials, PMPs and PMIs.

And so looking at whether something is safe to be in food or not safe to be in food, or whether it's being grown in a food crop or not being grown in a food crop, is something that we would have a lot more latitude in terms of what kind of decision we could make around how that particular trait in that particular crop could be field tested.

So we'll be in a much better position to factor in whether a certain trait is going to be in a food crop, or whether it's not. And if it's in a food crop, if it's something that has been, if there's been a food safety evaluation to say that it's safe to be in a food crop. And then if it's not, then we can factor that into whether we approve a permit, or what kinds of requirements we put on that permit.

MR. CAPLAN: So you'll be in a much better position to make those determinations if you have expanded authorities under the noxious weed provisions?

MS. SMITH: That's correct.

MR. CAPLAN: Is prohibiting the use of food crops for production of pharmaceuticals and industrial chemicals

an option on the table for the agency?

MS. SMITH: Right now everything is an option on the table. At the beginning of this process, the whole purpose of the process is to gather as many diverse perspectives on all of these issues. We'll pull them all together, and we'll use the environmental impact statement process for us to evaluate the different kinds of options available to us on many of these issues.

MR. CAPLAN: I guess also one quick question, if we're going to a few other points.

John, you mentioned the interagency discussions with the White House and the other agencies. I'm wondering if you're able to expand a little bit about what other, if you're able to discuss what other agencies are planning on doing based on, as a result of those discussions.

MR. TURNER: I really can't expound on their plans at all. I don't know if Cindy is any more enlightened than I am.

MS. SMITH: I think it's, what I can tell you is that EPA, FDA, and USDA participated in discussions with the White House to look at whether any of our respective agencies wanted to make any enhancements to their regulatory system. There was agreement that we would move forward in terms of taking advantage of authorities in the Plant Protection Act. But at this point, other agencies have not

announced their intentions to make any changes. That does not necessarily mean that there's not other things in the works.

At this point, I don't have another agency that is in a position for me to share on their behalf what their plans are. I would direct you to the other agencies.

MR. CAPLAN: Well, are you able to say whether or not you encouraged other agencies to take action?

MS. SMITH: We had a very thoughtful and intensive process, where we looked at all of the issues related to biotechnology regulation, and where we wanted to consider opportunities for enhancing the system. And so in some cases, that meant that we were saying here are some things we want to do, and then in some cases that meant there were suggestions that we were making to other agencies, as well.

MR. CAPLAN: I guess in part I'm asking because of this issue of whatever it's called, adventitious presence or so forth, that comes up a number of times in the Federal Register Notice.

Again, I don't think our position here is going to come as a great surprise to folks. But certainly this is one of the areas that we are most concerned about, in part because it seems, just based on some of the language in the notice itself, that things are headed in a direction of tolerating what we consider to be a very preventable

situation.

So for example, if I were to read number three, where you sort of reference regulating an organism based on minor unresolved risks. That language struck me as odd, because if it's an unresolved risk, it seems unusual to then be making the assertion already that it's minor.

And I think there are a number of references throughout here that refer to low risk and so forth. I think we're sort of equating what is also assumed to be low level of contamination with low risk. And we don't see it that way.

MS. SMITH: Can I clarify what we're talking about in number three?

MR. CAPLAN: Certainly.

MS. SMITH: And that's part of the reason why we want to have this give and take. We think we're speaking clearly. And what's been clear is when people come in and they look at what we're reading, they read something different.

What we're talking about in item number three is building flexibility into our deregulation process, essentially. Currently we, when something meets all of our safety requirements, then it can be approved for deregulation as a company wants to move it to commercialization.

One of the things that the National Academy has called for is that when there is a reason to consider to continue to gather information about a product, that there be a mechanism to do that. In other words, to gather some monitoring information for some period of time to address some issue.

What we're referring to here when we talk about these minor, unresolved risks, is we're talking about a product that comes before us that is largely safe, but there's some minor aspect of that where there's a science-based question that's not entirely answered. But it's only related to a low level of risk.

Building the flexibility into our deregulation process so that even though something comes before us, and you may believe it's ready for us to approve it to move into, let's say, the commercial stream as a result of coming through deregulation, what we're considering is building flexibility into the system, so that we can, for example, gather monitoring information or commission a study to gather monitoring information, to watch for some period of time the effects of some science-based issue that was related to that particular trait in that particular crop.

MR. CAPLAN: So you're saying that you would have resolved what you would consider to be all high to medium, what-have-you, risks that there are unresolved. The only

possibility of risk is what you're terming low level, is that right?

MS. SMITH: What we're saying is only if there was a very low level of risk. In other words, for us to put something through an approval or a deregulation process, safety, there needs to be data that shows safety.

And if there was something that came, and there was some low-level minor level of risk, not enough that we think that it would be a problem, but at the same time there's some science question that we'd like to gather some additional information on, allow us to be able to -- us or the company or a professional scientific society or some group -- to gather information after that's gone through our process. We're trying to build that kind of flexibility into the system.

MR. CAPLAN: Now, USDA's role in oversight of biotech is mostly in oversight of field trials and environmental assessment. And the Food and Drug Administration's oversight does not, as we know, require, there are no mandatory approvals at FDA. Companies go through a voluntary consultation process.

If you were to exempt, if there were categories for which you exempted certain crops in whatever stage, certain requirements, or there were certain, if you established certain components you rated for a system that

allowed for certain, for adventitious presence. Is there a way that FDA could then say we disagree with the Department of Agriculture's determination here, and we think there is a food safety risk?

MS. SMITH: Yes.

MR. CAPLAN: Is your exempting that crop making it impossible for that to then be an adulterant to the food supply? I mean, what is -- that's part of the reason I --

MS. SMITH: I'm going to give you a quick answer, and then I need to run. John is a good person to answer this, as well.

What we're talking about specifically for adventitious presence is that what we are looking at is establishing certain safety criteria. And if there was an intermittent or low level of the occurrence of a given event --

MR. CAPLAN: And where is this intermittent or low level? Where? Are we talking we are now in the food supply? Or are we talking --

MS. SMITH: Well, we're going to have to establish it. This is what we're looking at. It's kind of part of the whole process.

MR. CAPLAN: Okay.

MS. SMITH: But in terms of looking at when there would be times in which that occurrence would be exempted,

what we would have to do is establish criteria in order to make a decision about this time it's exempted, this time it's a violation of our regulations.

The criteria that we would develop, we would develop that in conjunction with EPA and FDA to make sure that all safety criteria are addressed among the three agencies.

So we wouldn't look at establishing criteria that would omit food safety. So FDA would not, we would not put FDA in a position to say we object, because we developed a criteria together among the three agencies.

And I apologize for having to go, but I'm leaving you in capable hands. I appreciate your time.

MR. CAPLAN: You as well.

MR. TURNER: I would reiterate that any criteria developed would be in close collaboration with the FDA. So it would not be us making decisions which were at odds with FDA.

The paper that came out of OSTP in August of 2002 of course came from the three agencies. And any low-level intermittent occurrence which is tolerated would have to have had some sort of food safety assessment at the early assessment.

MR. CAPLAN: Tom, I guess perhaps this is something that the agency is figuring out now. But are we

talking about the detection of a, say for example violation of the field testing stage? Or at what point are you making the determination that an adventitious presence is tolerable? There are 9,000 acre field trials -- of various crops. So are we talking there is detection determined at the field testing stage, and you are allowing crops, then at that point you consult FDA and say we found some contamination, and we want to talk about whether or not this is okay in the food supply? Or are you talking about you detect something --

MR. TURNER: At some point early on in the development of the crop, the applicant would have to go to FDA. So that very little in the way of field tests take place before they go to FDA, for an early safety assessment. That's what the August, 2002 document says.

MR. CAPLAN: Correct.

MS. BECH: And that document is focused on field testing.

MR. CAPLAN: Right. Now, I guess I'm wondering if you could tell me a little bit about, at this point, since there's information that I have not been able to get from the agency. But in terms of looking at the field trials that are going on, have been going on, is the agency doing its own testing of, say, neighboring fields to determine if there is, I guess some folks would call it contamination,

some would call it adventitious presence, in neighboring fields and so forth. Is the agency going out to test at what rate the pollen is traveling, at what rate animals are taking seeds, and so forth? Is that happening now? And if so, at what rate?

MR. TURNER: No, we're not testing neighboring fields around field tests at this time.

MR. HOFFMAN: There have been some field trials where some groups have done that. I think in the creeping bent grass, I think there was a group from the University of Colorado, Oregon State, that had done some testing. But it's the exception.

MR. CAPLAN: The exception that the institution that's conducting the field trial, or something --

MR. HOFFMAN: Or where the agency -- our agency is not doing that. But there are some examples where data is being collected at field trials to look at the extent of gene flow.

MR. CAPLAN: Okay. Thanks. I guess when we're talking about why we would need a system to address adventitious presence, is it fair to say that that is happening because the institution, from USC's perspective, is that happening because institutions are violating your field testing regulations? Is that why there would be adventitious presence in the first place? Is that a fair

assessment?

MR. TURNER: Actually, if something becomes mixed into the supply due to a violation, we wouldn't consider that adventitious presence. The agency would take action.

MR. CAPLAN: Okay.

MR. TURNER: So there is a certain amount, a very low level, which will occasionally occur just due to the biology and factors which are uncontrollable, in the way that routine field testing is done.

MR. CAPLAN: Okay. So adventitious presence is a different category than violation of USDA's field testing regulations. Adventitious presence refers exclusively to things like wind, that you just referred to?

MR. TURNER: There are a lot of definitions. But certainly what we've said is if it's the result of permit violations, it wouldn't be something which would be tolerated.

MR. CAPLAN: Now, is it USDA's belief that more can be done to prevent adventitious presence from occurring in the first place? So, for example, I know the agency changed some of its guidance for people conducting field trials really to crops engineers to produce pharmaceuticals and industrial chemicals. But do you think that the same types of approaches that were put forward there could be used to reduce instances of adventitious presence from

happening?

MR. TURNER: We certainly do. And the tiered risk assessment system that we're talking about in the NOI addresses it based on risk. And so for those things which shouldn't be there, you can apply those types of extraordinary measures, which should keep it out of the food supply.

Other things will have to be addressed through the early consultation with the FDA that we've just been through.

MR. CAPLAN: So the agency's thinking at this point is that the biofarm crops would require a certain, if we're thinking about it as a tiered system where it required more geographic isolation, or staggered planting times, but crops that the agency considers to be low risk, you would not do -- I don't know how to phrase it -- you would not do as much to prevent adventitious presence?

MR. TURNER: They would have different field testing standards. And it's a little inaccurate to say the agency. Part of what we're going to do is develop these criteria in conjunction with the other agencies, with EPA and FDA, because there's a food safety component. And we can consider the review status of the other agencies as we place them into these categories.

MR. CAPLAN: So in conjunction with the other

agencies, there would be categories of crops that you would be less concerned were there to be adventitious presence, if you could determine that those were, if you felt that they were to be low risk crops.

MR. TURNER: I think so. And remember at this point, these are concepts that we're considering. So you're asking very detailed questions, and it's very difficult to answer them in terms of what we're going to do. But there are ideas which we're considering, for which we're seeking input.

MR. CAPLAN: Okay. I guess back to the idea of certain, I guess, inspections and enforcement of these field trials. Do you think, is it the agency's thinking that doing some additional testing, say around field trials, would help you understand the rate at which there should be concern about pollen flow and so forth from these field trials? If the agency isn't going to field trials to say here is what's happening to the immediate neighbor or two neighbors down, or what-have-you, if that data isn't being hunted, it seems like that would hamper your ability to make determinations about how best to go about reporting --

MR. TURNER: We think that type of data is very important. And we're looking to the research community to produce that type of data. And the best way to produce it is under controlled experimental conditions.

So we're very interested in that. We actually commissioned the recent report on bioconfinement that you referred to. Very interested in that feedback. And we also are actively now seeking outside expertise on these compliance issues to understand about these issues.

And so we are seeking data on these types of things. But we don't have a program for field testing around all of these fields.

MR. CAPLAN: I'm wondering, the bioconfinement report I'm assuming is something that will play heavily into the development of this EIS.

MR. TURNER: We're going to certainly consider that report, and the other two reports from the National Academies which speak to our regulatory program.

MR. CAPLAN: I'm wondering if -- it's referenced here someplace -- the role of the states, number six briefly mentions considering establishing new mechanisms involving APHIS and the states. So that's specifically for, again, pharmaceutical and industrial compounds.

But I'm wondering more generally if the agency envisions a different relationship with the states in terms of oversight for this kind of engineering.

MS. BECH: I'll answer that. Because actually yesterday Cindy and I met with the National Association of State Departments of Agriculture and the Commissioners which

are in town this week, which you're probably aware of. And we had a very good discussion with them about some ideas, and how we can play more of a partnering role with the states in several ways.

One of the things we'd like to do is to hold a meeting with them very soon, to actually have them come in and talk to us about the EIS and the regs, and hear more about their concerns there, and be very active in that dialogue with them. As well as we're looking at some initiatives with inspections and compliance on our field trials, and working very closely with the states to leverage resources, including theirs, perhaps through some certification program that we could do.

So there are several initiatives that we've begun talking to them. Of course, in the past we've worked closely with them as well on our permits and, you know, getting concurrence from them, if it's going into their state, and things like that. So we are very much interested in strengthening that relationship, and have begun some very good discussions with them.

MR. CAPLAN: Okay, great. I'm wondering how the National Academy report, Environmental Acts of Transgenic Plants, I may have the title wrong, reference a sort of, I guess what they thought was a lack of emphasis -- not a lack of emphasis, but there had been an issue of long-term

monitoring that had been, inadequate attention paid by the agency and by others.

And I'm wondering how you think that plays into your formation of this EIS.

MR. TURNER: Well, one of the things that we've talked about already is this mechanism. If we think there is a need for monitoring -- you wouldn't monitor unless there was a risk. Hence, our language about a low-level risk. In those cases we could give an approval and require monitoring.

MR. CAPLAN: But if I'm remembering the report correctly, the agency, the National Academy also essentially said that much of the discussion over risk of genetic engineering crops at this point is lacking data on long-term monitoring to say that there is a category of, sort of a very clearly established category of low-risk genetically altered crops, because there hasn't been the long-term monitoring done.

MR. HOFFMAN: No, I don't think that's quite true. I think it was a study that came out this year, where they reported a monitoring for 10 years for three crops. And they came to the conclusion that, you know, a very predictable conclusion that there wasn't any risk.

MR. CAPLAN: Which study are you referring to?

MR. HOFFMAN: What's the name of the one, Crawley?

I think it came out in Nature.

So on the one hand, if what you're proposing are extremely expensive kinds of studies that to some extent have been done because no one had ever looked at them, and then now one -- I don't know how many millions of dollars that one study cost. And the conclusion was there was no effect. What they were specifically looking at was the persistence of, I think there was an herbicide-tolerant canola. They looked at the first three or four genetically engineered crops that were developed. And they found that none of those persisted in the environment.

So to some extent, these kinds of experiments, you know, are done when they can be done. But to do it on a routine basis like you're implying would be prohibitively expensive for very little return.

MR. CAPLAN: As I recall, the research in that particular study I read was looking at persistence, which is, I guess, one of a panoply of concerns related to even one subset of risk of genetic engineering, environmental risk.

And I guess a study that came out more recently, that I think was interesting to note, was UK Government funded research looking at also the three crops that, for which two of the three based on, again, only one subset of environmental risk, it was recommended that

commercialization not be approved. In the third crop, corn, the research was done using an herbicide that the UK and I think the UI is considering banning out of health concerns.

So here you have a case when the government looked into doing research on genetically engineered crops, and research that we think the Department of Agriculture in the United States has had a much longer track record, I think, in doing research in open-air planting of these crops. And yet the UK Government, in a shorter amount of time and much later in the game, is pointing to what we consider to be very important environmental risks.

So that research in the UK I think was important, but in a sense limited, because there are so many other risks to be examining. And yet I think there are many fundamental risks that remain largely unexplored. I think that research from the UK is an example of where one has to wonder why did that research happen years after field trial after field trial, even commercialization was authorized in this country, but yet the UK Government comes to a very different, and fundamentally different, understanding.

MR. HOFFMAN: Are you talking about the farm study experiments?

MR. TURNER: Yes, Neil and I were able to actually talk with our counterparts who regulate for the UK about those studies.

The type of risk they found were more due to the cropping system. It was because of the degree of weed control that they had that gave them a drop in the other end. You wouldn't get the same thing with the organic farmer if you hand-pulled all the weeds and got that same level of weed control.

It was not any direct effect of the herbicide itself. So I mean, it's the same type of effect you would get from different cropping systems, from tilling versus no tilling, from different varieties from what you choose to grow, all of which will affect the number and the type of weeds in a field.

MR. HOFFMAN: And I think your interpretation about what the UK Government, about saying that they shouldn't commercialize those crops, from reading the studies and talking to those, our counterparts in the UK, I distinctly did not come to that impression that they came to that conclusion. Just that they could say there was some measurable impact on some of the non-targets by, as John was saying, removing weeds. And you could do that by hand tilling, you could do it by a number of means.

And so I think that that conclusion is not what the UK Government said. They said that a measurable effect on non-targets. But they didn't come to the conclusion that they should not commercialize.

MS. BECH: You might be interested to know that we are preparing a response to the NAS reports, in which we'll be addressing your recommendations. And due to the time and the limit, I don't know if you want to maybe move past this, and if you have some more issues. Or you know, if you'd like to spend some more time talking about this particular point, or move on.

But we are responding to the reports. And we have had several things, such as the science panels come in and looked at non-target effects, as well as post-commercialization monitoring. They've given us some input into that, and we're analyzing what they provided to us right now. So you might be interested in later on continuing the discussion and seeing what our response would be.

MR. CAPLAN: I would. I mean, I guess my basic point is wondering why that research was done so much later than it should have been. And I think that's indicative of what we're talking about when we assume that crops will have low risk on the environment, when in fact --

MS. BECH: Well, one of the things that we're interested in hearing, of course -- and this has changed as well as in the written comments -- is recommendations and concerns that you have. And so that's certainly something we would encourage you to say. If you think more research

should be done earlier, you know, those are very good recommendations to be making for us to consider.

MR. CAPLAN: I guess just going forward from this, I'm wondering, when we heard that this notice was coming, Cindy mentioned that there were going to be hearings, several public hearings. I'm wondering if you know the status of that effort, of when they will begin.

MR. TURNER: That would be much later in the process. There's going to be multiple opportunities for input. This is the first. There will be a draft EIS at some point that will be out for comment.

Then I think it's while the proposed rule is out, we had talked about having public meetings at that time.

MS. BECH: Yes, there will be several opportunities as we move. This is a very informal opportunity right now at the very beginning stage of it, to have this dialogue with you. So probably more of the formal public hearings will come later.

MR. CAPLAN: Can you sort of walk me through it? So you will receive comments on this when you conclude at the end of next month. So then what are the next couple of steps for the agency?

MR. TURNER: Well, the first step, and it's a huge step, is to write an environmental impact statement. So we're gathering up all the issues people have. We will

distill those down into issues which we feel need to be addressed. Then we'll consider changes, revisions we can make in our regulations that would address those issues, and explore possibilities which seem viable.

At the end of that process you would have your environmental impact statement. And that should direct, then, the writing of the proposed rule. So we're shooting to have a draft of the environmental impact statement next fall some time.

MR. CAPLAN: Is next fall -- it's always tricky, the word next -- is that fall of 2005? Or is next fall --

MR. TURNER: 2004. This coming fall.

MR. CAPLAN: Okay.

MR. TURNER: And during that time, we would also probably start writing the rule.

MS. BECH: And of course, the next steps would be published in the Federal Register Notice, you know, any kind of proposed rule. And then that would proceed with public comment periods and things like that.

MR. CAPLAN: Okay. That's all I have. I actually brought some copies of a report that we wrote, that I wrote last summer. And I wrote it on six, I think. So I would strongly encourage you to take it. They're heavy; I don't want to take them back with me. They sort of outline what we consider to be -- this was written, of course, long

before this Federal Register Notice -- what we consider to be some of the concerns that we have with oversight at USDA regarding environmental risks in genetic engineering.

So I'll leave those with you. I think those are really the main questions and concerns I have with the notice. And so I'll leave it there.

I mean, again, obviously I think this is just a great opportunity for myself and a lot of my colleagues, both from all perspectives, to come and have an opportunity to hear from you, and also put forward what we consider to be some of our main concerns about the notice. And we really sincerely appreciate the opportunity to do that, and look forward to working with you more as we go forward from here.

MR. TURNER: Very good.

MS. BECH: Does anyone have any comments or questions?

MR. HOFFMAN: I just had a question. You mentioned PIRG had two philosophies about PMPs. One was that you were against the production in food crops, and the other was against the open-air testing in food or non-food crops.

And I certainly understand the concerns with the first case. And I was interested to hear you elaborate on some of the more specific concerns about producing PMPs in

non-food crops, you know, in the open air.

MR. CAPLAN: I guess just the concern is that just sort of, out of an abundance of caution, to ensure that there is no problem with anything. We were talking about a whole different category of risk in certain cases with these crops. And so to ensure that they are, to do the best possible job of ensuring that there is no contamination of that.

MR. HOFFMAN: Is it a concern of contaminating the food supply? Or is it effects on non-target organisms?

MR. CAPLAN: Certainly both of those. I think non-targets are a concern, soil is a concern, and commingling is a concern. I guess a range of concerns that we think would really be largely mooted were this to be conducted indoors, or in some other more confined --

MS. BECH: Of course, commingling could occur along the process even after it's taken out of the contained facility to be processed. Just because you might grow it contained would not necessarily address all the commingling issues.

MR. CAPLAN: You're right. I can't make it more clear to anyone involved in this type of research that by, for example, requiring it to be conducted in a, say, contained environment, that would be one of several steps to make it very clear that failure to comply with regulations

would meet with very serious consequences.

MS. BECH: Anything else? Well, we thank you very much for coming in.

MR. CAPLAN: I thank you very much for having me.

(Whereupon, at 4:00 p.m., the meeting in the above-entitled matter was adjourned.)

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REPORTER'S CERTIFICATE

CASE TITLE: PUBLIC INTEREST RESEARCH GROUP MEETING
HEARING DATE: February 25, 2004
LOCATION: College Park, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 25, 2004

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